Health and Human Services (HHS) is given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 between the ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This Study Team is charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purposes of this meeting is to review the goals, methods, and schedule of the project, discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns and provide advice to CDC.

Matters to Be Discussed: Agenda items include a presentation from the National Center for Environmental Health (NCEH) and/or its contractor regarding the information gathering project that is underway. There will be time for public input, questions, and comments. All agenda items are subject to change as priorities dictate.

Contact Persons for Additional Information: Phillip Green, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, N.E. (E-39), Atlanta, GA 30333, telephone 404/498-1717, fax 404/498-1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: June 20, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02-16089 Filed 6-25-02; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E-1402]

Determination of Regulatory Review Period for Purposes of Patent Extension; BETAXON

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BETAXON and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product BETAXON (levobetaxolol). BETAXON is indicated for lowering intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BETAXON (U.S. Patent No. 4,911,920) from Alcon Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 17, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BETAXON represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for BETAXON is 947 days. Of this time, 765 days occurred during the testing phase of the regulatory review period, while 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: July 23, 1997. The applicant claims June 23, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 23, 1997, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: August 26, 1999. The applicant claims August 25, 1999, as the

date the new drug application (NDA) for BETAXON (NDA 21–114) was initially submitted. However, FDA records indicate that NDA 21–114 was submitted on August 26, 1999.

3. *The date the application was approved:* February 23, 2000. FDA has verified the applicant's claim that NDA 21–114 was approved on February 23, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 579 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by August 26, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 23, 2002. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02–16052 Filed 6–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Traumatic Brain Injury Program; State Grants for Traumatic Brain Injury

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that about $1.2 million in fiscal year (FY) 2002 funds is available for up to 11 State Grants for Traumatic Brain Injury (TBI). The purpose of the TBI program is to assist individuals who have sustained a traumatic brain injury in obtaining health care and other services. Awards will be made in three categories: (1) Planning Grants, to assist States in developing the infrastructure needed to implement a State TBI program; (2) Implementation Grants, to assist States in moving toward statewide systems that assure access to comprehensive and coordinated TBI services, and (3) Post Demonstration Grants, to assist States which have successfully completed a TBI Implementation Grant. HRSA expects to award two Planning Grants, one Implementation Grant, and eight Post-Demonstration Grants this fiscal year. All awards will be made under the program authority of the Public Health Service Act, Title XII, section 1252 (42 U.S.C. 300d–52), and will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Planning Grants may be approved for up to two years; with awards of up to $75,000. The Implementation Grant may be approved for up to 3 years; the award will be up to $200,000. Post Demonstration Grants will be approved for only one year; awards will be up to $100,000. Funding beyond FY 2002 is contingent upon the availability of funds.

DATES: Applicants are requested to notify MCHB of their intent to apply by July 19, 2002. The deadline for receipt of applications is August 2, 2002. Applications will be considered "on time" if they are either received on or before the deadline date or postmarked on or before the deadline date. The projected award date is September 29, 2002.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1–877–477–2123 (1–877–HRSA–123) or register on-line at: *http://www.hrsa.gov/g_order3.htm* directly. The Traumatic Brain Injury State Grant Program uses the standard Form PHS 5161–1 (rev. 7/00) for applications (approved under OMB No. 0920–0428). Applicants must use the following Catalog of Federal Domestic Assistance (CFDA) numbers to request applications kits: Implementation Grants, #93.234A; Planning Grants, #93.234B; Post Demonstration Grants, #93.234C. The CFDA is a Government-wide compendium of enumerated Federal programs, project services, and activities that provide assistance. All applications must be mailed or delivered to Grants Management Officer, MCHB: HRSA Grants Application Center, 901 Russell Avenue Gaithersburg, MD 20897: telephone 1–877–477–2123: E-mail: *hrsagac@hrsa.gov.*

Necessary application forms and an expanded version of this **Federal Register** notice may be downloaded in either Microsoft Office 2000 or Adobe Acrobat format (.pdf) from the MCHB Home Page at *http://www.mchb.hrsa.gov.* Please contact Joni Johns, at *jjohns@hrsa.gov,* or 301–443–2088, if you need technical assistance in accessing the MCHB Home Page via the Internet.

This notice will appear on the HRSA Home Page at *http://www.hrsa.gov/.* **Federal Register** notices are found on the World Wide Web by following instructions at: *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

Letter of Intent: Notification of intent to apply should be directed to Betty Hastings, M.S.W., by email, *bhastings@hrsa.gov;* or mail, MCHB, HRSA; TBI Program, Parklawn Building, Room 18A–38; 5600 Fishers Lane; Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Betty Hastings, M.S.W., 301–443–5599, or email: *bhastings@hrsa.gov* (for questions specific to project objectives and activities of the program; or the required Letter of Intent); Marilyn Stewart, 301–443–9022, email *mstewart@hrsa.gov* (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION:

Traumatic Brain Injury Program Background and Objectives

Traumatic brain injury (TBI) is sudden physical damage to the brain, often caused by motor vehicle accidents, falls, sports injuries, violent crimes, or child abuse. TBI can result in physical, behavioral, and/or mental changes, depending on the areas of the brain that are injured. TBI is the leading cause of death and disability among young people in the United States. Approximately 200,000 Americans die each year from traumatic injuries. An additional half million are hospitalized. About 10 percent of the surviving individuals have mild to moderate problems that threaten their ability to live independently. Another 200,000 have serious problems that may require institutionalization or some other form of close supervision.

The number of people surviving TBI has increased significantly in recent